

# Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus

**Policy # 00261**

Original Effective Date: 06/16/2010

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*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Confocal Laser Endomicroscopy is addressed separately in medical policy 00416.*

## When Services Are Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider radiofrequency ablation (RFA) for treatment of Barrett esophagus (BE) with either high-grade dysplasia (HGD) or low-grade dysplasia (LGD) to be **eligible for coverage.\*\***

## When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers radiofrequency ablation (RFA) for treatment of Barrett esophagus (BE) in the absence of dysplasia to be **investigational.\***

Based on review of available data, the Company considers cryoablation for Barrett esophagus (BE), with or without dysplasia to be **investigational.\***

## Background/Overview

### Diagnosis

Radiofrequency ablation for Barrett esophagus with high-grade dysplasia may be used in combination with endoscopic mucosal resection (EMR) of nodular or visible lesions.

### Barrett Esophagus and Risk of Esophageal Carcinoma

The esophagus is normally lined by squamous epithelium. Barrett Esophagus (BE) is a condition in which the normal squamous epithelium is replaced by specialized columnar-type epithelium, known as intestinal metaplasia, in response to irritation and injury caused by gastroesophageal reflux

## Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus

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disease. Occurring in the distal esophagus, BE may be of any length; it may be focal or circumferential and can be seen on endoscopy as being a different color than the background squamous mucosa. Confirmation of BE requires a biopsy of the columnar epithelium and microscopic identification of intestinal metaplasia.

Intestinal metaplasia is a precursor to esophageal adenocarcinoma, which is thought to result from a stepwise accumulation of genetic abnormalities in the specialized epithelium, resulting in the phenotypic expression of histologic features from low grade dysplasia (LGD), to high-grade dysplasia (HGD), to carcinoma. Two large epidemiologic studies published in 2011 reported the risk of progression to cancer in patients with BE. One reported the rate of progression to cancer in more than 8000 patients with a mean duration of follow-up of 7 years (range, 1 to 20 years). The de novo progression to cancer from BE at 1 year was 0.13%. The risk of progression was reported as 1.4% per year in patients with LGD and 0.17% per year in patients without dysplasia. This incidence translates into a risk of 10 to 11 times that of the general population. The other study identified more than 11,000 patients with BE and, after a median follow-up of 5.2 years, it reported that the annual risk of esophageal adenocarcinoma was 0.12%. Detection of LGD on index endoscopy was associated with an incidence rate for adenocarcinoma of 5.1 cases per 1000 person-years, and the incidence rate among patients without dysplasia was 1.0 case per 1000 person-years. Risk estimates for patients with HGD were slightly higher. The reported risk of progression to cancer in BE in older studies was much higher, with an annual incidence of risk of 0.4% to 0.5% per year, with risk estimated at 30 to 40 times that of the general population. Current surveillance recommendations have been based on these higher risk estimates.

There are challenges in diagnostically differentiating between nondysplastic BE and BE with LGD; they are important when considering treatment for LGD. Both sampling bias and interobserver variability have been shown to be problematic. Therefore, analysis of progression to carcinoma in BE with intestinal metaplasia versus LGD is difficult. Initial diagnosis of BE can also be a challenge with respect to histologic grading because inflammation and LGD can share similar histologic characteristics.

One approach to risk-stratify patients with an initial diagnosis of LGD has been to use multiple pathologists, including experts in gastrointestinal histopathology, to confirm the initial diagnosis of LGD. There is a high degree of interobserver variability among the pathology readings of LGD versus inflammatory changes, and the resultant variability in pathology diagnosis may contribute to the variable rates of progression of LGD reported in the literature. Kerkhof et al (2007) reported that, in patients with an initial pathologic diagnosis of LGD, review by an expert pathologist would result in the initial diagnosis being downgraded to nondysplasia in up to 50% of cases. Curvers et al (2010) tested this hypothesis in 147 patients with BE who were given an initial diagnosis of LGD. All pathology slides were read by 2 expert gastrointestinal pathologists with extensive experience in BE; disagreements among experts in the readings were resolved by consensus. Once this process was completed, 85% of initial diagnoses of LGD were downgraded to nondysplasia, leaving 22 (15%)



## Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus

Policy # 00261

Original Effective Date: 06/16/2010

Current Effective Date: 02/10/2025

of 147 patients with a confirmed diagnosis of LGD. All patients were followed for a mean of 5.1 years for progression to HGD or cancer. For patients with confirmed LGD, the rate of progression was 13.4%, compared with 0.5% for patients who had been downgraded to nondysplasia.

The strategy of having LGD confirmed by expert pathologists is supported by the results of a randomized controlled trial by Phoa et al (2014), which required confirmation of LGD by a central expert panel following initial diagnosis by a local pathologist. Of 511 patients with an initial diagnosis of LGD, 264 (52%) were excluded because the central expert panel reassigned the classification of LGD, most often from LGD to indefinite or nondysplasia. These findings were further confirmed in a retrospective cohort study by Duits et al (2015) who reported on 293 BE cases with LGD diagnosed over an 11-year period and submitted for expert panel review. In this sample, 73% of subjects were downstaged.

### **Management of Barrett Esophagus**

The management of BE includes the treatment of gastroesophageal reflux disease and surveillance endoscopy to detect progression to HGD or adenocarcinoma. The finding of HGD or early-stage adenocarcinoma warrants mucosal ablation or resection (either endoscopic mucosal resection [EMR] or esophagectomy).

EMR, either focal or circumferential, provides a histologic specimen for examination and staging (unlike ablative techniques). One 2007 study provided long-term results for EMR in 100 consecutive patients with early Barrett-associated adenocarcinoma (limited to the mucosa). The 5-year overall survival was 98% and, after a mean of 36.7 months, metachronous lesions were observed in 11% of patients. In a review by Pech and Ell (2009), the authors stated that circumferential EMR of the entire segment of BE leads to a stricture rate of 50%, and recurrences occur at a rate of up to 11%.

### **Ablative Techniques**

Available mucosal ablation techniques include several thermal (multipolar electrocoagulation [MPEC], argon plasma coagulation [APC], heater probe, neodymium-doped yttrium aluminum garnet [Nd:YAG] laser, potassium titanyl phosphate [KTP]-YAG laser, diode laser, argon laser, cryoablation) or nonthermal (5-aminolevulinic acid, photodynamic therapy) techniques. In a randomized phase 3 trial reported by Overholt et al (2005), photodynamic therapy was shown to decrease significantly the risk of adenocarcinoma in BE.

Radiofrequency ablation affects only the most superficial layer of the esophagus (ie, the mucosa), leaving the underlying tissues unharmed. Measures of efficacy for the procedure are the eradication of intestinal metaplasia and the postablation regrowth of the normal squamous epithelium. (Note: The eradication of intestinal metaplasia does not leave behind microscopic foci). The HALO system uses radiofrequency energy and consists of 2 components: an energy generator and an ablation catheter. Reports of the efficacy of the HALO system in ablating BE have been as high as 70% (comparable with alternative methods of ablation [eg, APC, MPEC]), and even higher in some



## Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus

Policy # 00261

Original Effective Date: 06/16/2010

Current Effective Date: 02/10/2025

reports. The incidence of leaving behind microscopic foci of intestinal metaplasia has been reported to be between 20% and 44% with APC and 7% with MPEC; studies using the HALO system have reported 0%. Another potential advantage of the HALO system is that it is an automated process that eliminates operator-dependent error, which may be seen with APC or MPEC. Cryotherapy allows for the treatment of uneven surfaces and can be administered as either a spray therapy or a balloon catheter.

The risk of treating HGD or mucosal cancer solely with ablative techniques is undertreatment for approximately 10% of patients with undetected submucosal cancer, in whom esophagectomy would have been required.

### **FDA or Other Governmental Regulatory Approval**

#### **U.S. Food and Drug Administration (FDA)**

In 2005, the HALO360 (now Barrx™‡ 360 RFA Balloon Catheter; Barrx Medical; acquired by Covidien in 2012 [now Medtronic]) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process and, in 2006, the HALO90 (now Barrx™‡ 90 RFA Focal Catheter) received clearance. The FDA labeled indications are for use in coagulation of bleeding and nonbleeding sites in the gastrointestinal tract and include the treatment of BE. Other focal ablation devices from Barrx include the Barrx™‡ 60 RFA Focal Catheter, the Barrx™‡ Ultra Long RFA Focal Catheter, the Barrx™‡ Channel RFA Endoscopic Catheter.

FDA product code: GEI.

In 2007, the CryoSpray Ablation™‡ System (formerly the SprayGenix Cryo Ablation system; CSA Medical) was cleared for marketing by the FDA through the 510(k) process for use as a “cryosurgical tool for destruction of unwanted tissue in the field of general surgery, specifically for endoscopic applications.” The CryoBalloon Ablation System has also been cleared by the FDA through the 510(k) process for use as a cryosurgical tool in surgery for endoscopic applications, including ablation of BE with dysplasia. The next-generation C2 CryoBalloon Ablation System was introduced in 2018.

FDA product code: GEH.

In 2002, the Polar Wand®‡ device (Chek-Med Systems), a cryosurgical device that uses compressed carbon dioxide, was cleared for marketing by the FDA through the 510(k) process. Indications for use are “ablation of unwanted tissue in the fields of dermatology, gynecology, general surgery, urology, and gastroenterology.”



## Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus

Policy # 00261

Original Effective Date: 06/16/2010

Current Effective Date: 02/10/2025

### **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

### **Description**

In Barrett esophagus (BE), the normal squamous epithelium is replaced by specialized columnar-type epithelium, known as intestinal metaplasia. Intestinal metaplasia is a precursor to adenocarcinoma and may be treated with mucosal ablation techniques such as radiofrequency ablation (RFA) or cryoablation.

### **Summary of Evidence**

For individuals who have Barrett esophagus (BE) with high-grade dysplasia (HGD) who receive endoscopic radiofrequency ablation (RFA), the evidence includes a randomized controlled trial (RCT) comparing radical endoscopic resection with focal endoscopic resection followed by RFA, 1 RCT comparing RFA with surveillance alone, and a systematic review evaluating RCTs and a number of observational studies, some of which compared RFA with other endoscopic treatment modalities. Relevant outcomes are change in disease status, morbid events, and treatment-related morbidity and mortality. The available evidence has shown that using RFA to treat BE with HGD is at least as effective in eradicating HGD as other techniques, with a lower progression rate to cancer, and may be considered an alternative to esophagectomy. Evidence from at least 1 RCT has demonstrated higher rates of eradication than surveillance alone. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have BE with low-grade dysplasia (LGD) who receive endoscopic RFA, the evidence includes at least 3 RCTs comparing RFA with surveillance alone, a number of observational studies, and systematic reviews of these studies. Relevant outcomes are change in disease status, morbid events, and treatment-related morbidity and mortality. For patients with confirmed LGD, evidence suggests that RFA reduces progression to HGD and adenocarcinoma. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have BE without dysplasia who receive endoscopic RFA, the evidence includes single-arm studies reporting outcomes after RFA. Relevant outcomes are change in disease status, morbid events, and treatment-related morbidity and mortality. The available studies have suggested that nondysplastic metaplasia can be eradicated by RFA. However, the risk-benefit ratio and the net effect of RFA on health outcomes are unknown. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.



## Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus

Policy # 00261

Original Effective Date: 06/16/2010

Current Effective Date: 02/10/2025

For individuals who have BE with or without dysplasia who receive endoscopic cryoablation, the evidence includes nonrandomized studies and systematic reviews of those studies reporting outcomes after cryoablation. Relevant outcomes include change in disease status, morbid events, and treatment-related morbidity and mortality. These studies have generally demonstrated high rates of eradication of dysplasia. Recent observational studies comparing RFA with cryoablation show similar outcomes. However, there are no RCTs comparing cryoablation with surgical care or RFA. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **Supplemental Information**

#### **Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

#### **2012 Input**

In response to requests, input was received from reviewers at 6 academic medical centers and from 1 subspecialty medical society while this policy was under review in 2012. Input related to the treatment of low-grade dysplasia (LGD) was mixed, with 2 reviewers stating that radiofrequency ablation (RFA) for LGD should be investigational, 3 indicating that it should be medically necessary, and 2 indicating that it was a split decision. There was a general consensus among reviewers that there are subsets of patients with LGD who have a higher risk and should, therefore, be treated. Reviewers mentioned that factors useful in defining higher risk populations for whom treatment is warranted are the confirmation of LGD diagnosis by multiple pathologists and/or the application of clinical high-risk factors such as lesion length.

#### **2009 Input**

In response to requests, input was received from 3 academic medical centers and 1 subspecialty medical society (with 12 reviewers) while this policy was under review in 2009. All reviewers agreed that RFA (cryoablation was not included in the request) should be considered medically necessary for the treatment of Barrett esophagus (BE) with high-grade dysplasia (HGD). Reviewers were split for the use of RFA for LGD, with 9 considering it medically necessary and 4 considering it investigational.

#### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given





## Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus

Policy # 00261

Original Effective Date: 06/16/2010

Current Effective Date: 02/10/2025

to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### **American College of Gastroenterology**

In 2022, the American College of Gastroenterology (ACG) updated guidelines on the diagnosis and management of BE, which made statements about ablation techniques. The ACG recommends ablation of remaining BE tissue when endoscopic eradication therapy is chosen for patients with LGD, HGD, or intramucosal carcinoma. Both RFA and cryoablation are discussed in the ACG guideline without a specific recommendation; however, the guideline notes the lack of randomized controlled trials (RCTs) for cryoablation methods and the more established evidence for RFA. The ACG does recommend cryotherapy as an alternative in patients unresponsive to RFA.

### **American Gastroenterological Association**

In 2024, the American Gastroenterological Association (AGA) published a clinical guideline on the role of endoscopic therapy in patients with BE and related neoplasia.

The AGA guideline made 5 recommendations for endoscopic eradication of BE:

- "In individuals with BE with HGD, the AGA recommends EET over surveillance. (Strong recommendation, moderate certainty of evidence)"
- "In individuals with BE with LGD, the AGA suggests for EET over surveillance. Patients who place a higher value on the well-defined harms and lower value on the benefits (which are uncertain) regarding reduction of esophageal cancer mortality would reasonably select surveillance endoscopy. (Conditional recommendation, low certainty of evidence)"
- "In individuals with NDBE [nondysplastic BD], the AGA suggests against the routine use of EET. (Conditional recommendation, very low certainty of evidence)"
- "In patients undergoing EET, the AGA suggests resection of visible lesions followed by ablation of the remaining BE segment over resection of the entire BE segment. (Conditional recommendation, very low certainty of evidence)"
  - "RFA is the preferred ablative modality."
- "In individuals with BE with visible neoplastic lesions that are undergoing endoscopic resection, the AGA suggests the use of either EMR [endoscopic mucosal resection] or ESD [endoscopic submucosal resection] based on lesion characteristics. (Conditional recommendation, very low certainty of evidence)"

### **American Society for Gastrointestinal Endoscopy**

In 2018, the American Society for Gastrointestinal Endoscopy (ASGE) issued guidelines on the role of endoscopy in BE-associated dysplasia and intramucosal cancer. These guidelines made the following recommendations on endoscopic eradication therapy, consisting of endoscopic mucosal resection of visible lesions and ablative techniques that include RFA and cryotherapy (see Table 1).



## Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus

Policy # 00261

Original Effective Date: 06/16/2010

Current Effective Date: 02/10/2025

**Table 1. ASGE Guidelines on Use of Endoscopy for Barrett Esophagus and Intramucosal Cancer**

<b>Recommendation</b>	<b>SOR</b>	<b>QOE<sup>a</sup></b>
In BE patients with LGD and HGD being considered for EET, we suggest confirmation of diagnosis by at least 1 expert GI pathologist or panel of pathologists compared with review by a single pathologist.	Conditional	Low
In BE patients with LGD, we suggest EET compared with surveillance; however, patients who place a high value on avoiding adverse events related to EET may choose surveillance as the preferred option.	Conditional	Moderate
In BE patients with confirmed HGD, we recommend EET compared with surveillance.	Strong	Moderate
In BE patients with HGD/IMC, we recommend against surgery compared with EET.	Strong	Very low quality
In BE patients referred for EET, we recommend endoscopic resection of all visible lesions compared with no endoscopic resection of visible lesions.	Strong	Moderate
In BE patients with visible lesions who undergo endoscopic resection, we suggest ablation of the remaining Barrett’s segment compared with no ablation.	Conditional	Low
In BE patients with dysplasia and IMC referred for EET, we recommend against routine complete endoscopic resection of entire Barrett’s segment compared with endoscopic resection of visible lesion followed by ablation of remaining Barrett’s segment.	Strong	Very low
In BE patients with dysplasia and IMC who have achieved CE-IM after EET, we suggest surveillance endoscopy versus no surveillance.	Conditional	Very low

BE: Barrett esophagus; CE-IM: complete eradication of intestinal metaplasia; EET: endoscopic eradication therapy; GI: gastrointestinal; HGD: high-grade dysplasia; IMC: intramucosal cancer; LGD: low-grade dysplasia; QOE: quality of evidence; SOR: strength of recommendation.

<sup>a</sup>Quality assessed using GRADE system.

### National Comprehensive Cancer Network

National Comprehensive Cancer Network Guidelines (v.4.2024) on esophageal and esophagogastric junction cancers make recommendations about BE and early-stage esophageal adenocarcinomas. For primary treatment; “The goal of endoscopic therapy [by endoscopic mucosal resection (EMR), endoscopic submucosal dissection (ESD), and/or ablation] is the complete removal or eradication of





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early-stage disease [pTis, pT1a, and selected superficial pT1b without LVI] and pre-neoplastic tissue (Barrett esophagus)."

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

**Table 2. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
<i>Unpublished</i>			
NCT01961778	Prospective Randomized Trial Comparing Radiofrequency Ablation (Barrx <sup>TM†</sup> ) and Cryotherapy (truFreeze <sup>TM†</sup> ) for the Treatment of Barrett's Esophagus With High-Grade Dysplasia and/or Early Adenocarcinoma	50	Feb 2020 (Last update posted Jan 2022)

NCT: national clinical trial.

<sup>a</sup>Denotes industry sponsored or co-sponsored trial.

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## Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus

Policy # 00261

Original Effective Date: 06/16/2010

Current Effective Date: 02/10/2025

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## Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus

Policy # 00261

Original Effective Date: 06/16/2010

Current Effective Date: 02/10/2025

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### **Policy History**

Original Effective Date: 06/16/2010

Current Effective Date: 02/10/2025

06/03/2010 Medical Policy Committee approval



## Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus

Policy # 00261

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Current Effective Date: 02/10/2025

06/16/2010 Medical Policy Implementation Committee approval. New policy.

05/05/2011 Medical Policy Committee approval

05/18/2011 Medical Policy Implementation Committee approval. No change to coverage.

04/12/2012 Medical Policy Committee review

04/25/2012 Medical Policy Implementation Committee approval. Radiofrequency ablation for treatment of Barrett's esophagus with low-grade dysplasia was changed from investigational to eligible for coverage when the initial diagnosis of low-grade dysplasia is confirmed by a second pathologist who is an expert in GI pathology. Added that treatment of Barrett's esophagus with low-grade dysplasia in any other situation is investigational.

03/04/2013 Coding revised

04/04/2013 Medical Policy Committee review

04/24/2013 Medical Policy Implementation Committee approval. No change to coverage.

06/25/2013 Medical Policy Implementation Committee approval. Retired medical policy.

01/09/2014 Medical Policy Committee review

01/15/2014 Medical Policy Implementation Committee approval. "Based on review of available data, the Company considers radiofrequency ablation for treatment of Barrett's esophagus in the absence of dysplasia" was changed from investigational to not medically necessary. Dropped the requirement of a second pathologist from coverage section. Brought back from retired status.

01/08/2015 Medical Policy Committee review

01/21/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.

01/07/2016 Medical Policy Committee review

01/22/2016 Medical Policy Implementation Committee approval. RFA for treatment of BE in the absence of dysplasia is considered investigational.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

01/05/2017 Medical Policy Committee review

01/18/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

01/04/2018 Medical Policy Committee review

01/17/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

01/10/2019 Medical Policy Committee review

01/23/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

01/03/2020 Medical Policy Committee review

01/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.



## Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus

Policy # 00261

Original Effective Date: 06/16/2010

Current Effective Date: 02/10/2025

01/07/2021 Medical Policy Committee review  
01/13/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
10/01/2021 Coding update  
01/06/2022 Medical Policy Committee review  
01/12/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
01/05/2023 Medical Policy Committee review  
01/11/2023 Medical Policy Implementation Committee approval. Title changed from “Endoscopic Radiofrequency Ablation or Cryoablation for Barrett’s Esophagus” to “Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus”. Changed “Barrett’s” to “Barrett” throughout the policy. Coverage eligibility unchanged.  
01/04/2024 Medical Policy Committee review  
01/10/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
01/02/2025 Medical Policy Committee review  
01/08/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 01/2026

### **Coding**

*The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

*The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.*



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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	43229, 43270
HCPCS	No codes
ICD-10 Diagnosis	D13.0, K22.70, K22.710, K22.711, K22.719, K22.81-K22.89

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  1. Consultation with technology evaluation center(s);
  2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  3. Reference to federal regulations.

\*\*Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally





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recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

